June 12, 2019

New Deantronics Taiwan Ltd
℅ Craig Coombs
President
Coombs Medical Device Consulting, Inc
1193 Sherman St
Alameda, California 94501

Re: K191064
Trade/Device Name: Argon Handset
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 19, 2019
Received: April 22, 2019

Dear Craig Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191064

Device Name
Argon Handset

Indications for Use *(Describe)*
The Argon Handset is an electrosurgical accessory intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar standard or argon-enhanced electrosurgery is desired. The electrosurgical energy is controlled by the electrosurgical generator during cutting and coagulation and the argon gas flow is controlled by the argon gas delivery system, via the Argon Handset, during argon-shrouded cutting and argon-enhanced coagulation. When the Argon Handset is activated in the argon-enhanced mode, argon gas plasma is created between the electrode and target tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	New Deantronics Taiwan Ltd. 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng District, New Taipei City 23675, Taiwan R.O.C. Tel: (886) 2-2268-1726 Fax: (886) 2-2268-3800
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140
Device Common Name:	Electrosurgical accessory
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class 2, GEI
Device Proprietary Name:	Argon Handset

Predicate Device Information:

Predicate Device:	Valleylab Force Argon II Argon Enhanced Electrosurgical System
Predicate Device Manufacturer:	Valleylab, Inc.
Predicate Device Common Name:	Electrosurgical accessory
Predicate Device Premarket Notification #	K964636
Predicate Device Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Predicate Device Class & Product Code:	Class 2, GEI

B. Date Summary Prepared

11 June 2019

C. Description of Device

The Argon Handset is intended to be used in electrosurgical procedures where monopolar standard or argon enhanced electrosurgery is desired. The pre-installed blade electrode is used in open surgery, while the longer argon electrodes can replace the blade electrode to be used in minimally invasive procedure. The Argon Handset has to be in conjunction with an electrosurgical generator, argon gas delivery system and patient return electrode. During the operation, the argon handset performs like a standard electrosurgical pencil, while it receives

both the argon gas and high frequency current, and delivers the electrosurgical energy onto a target tissue for either a standard or argon-enhanced procedure.

The Argon Handset is sold in sterile packaging and is a single use device. These devices can be used in hospitals and are used by trained professionals only.

The Argon Handset is designed for fitting into the Covidien Argon Gas Delivery Unit II or Force™ GSU Argon Gas Delivery Systems, and Covidien Force EZ™ or Force FX™ series electrosurgical generators.

The blade electrode of the Argon Handset is replaceable by the New Deantronics Argon Electrode Series or Covidien E35XX series Argon Electrodes depending on the surgical procedures required.

D. Indications for Use

The Argon Handset is an electrosurgical accessory intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar standard or argon-enhanced electrosurgery is desired. The electrosurgical energy is controlled by the electrosurgical generator during cutting and coagulation and the argon gas flow is controlled by the argon gas delivery system, via the Argon Handset, during argon-shrouded cutting and argon-enhanced coagulation. When the Argon Handset is activated in the argon-enhanced mode, argon gas plasma is created between the electrode and target tissue.

E. Comparison to Predicate Device

As described below, the application Argon Electrodes is substantially equivalent in intended use, technology, design and physician use to the predicate Force Argon II Argon Enhanced Electrosurgical System (K964636).

Tabular Comparison of the Argon Handset to Predicate Device

Feature	**Application Device:** Argon Handset	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The Argon Handset is an electrosurgical accessory intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar standard or argon enhanced electrosurgery is desired. The electrosurgical energy is controlled by the electrosurgical generator during cutting and coagulation and the argon gas flow is controlled by the argon gas delivery system, via the Argon Handset, during argon-shrouded cutting and argon-enhanced coagulation. When the Argon Handset is activated in the argon-enhanced mode, argon gas plasma is created between the electrode and target tissue.	The Force Argon II Enhanced Electrosurgical System is intended for use in both open, laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar electrosurgery (cutting and coagulation) is normally used. The Force Argon II Argon Enhanced Electrosurgical System provides a controlled flow of argon to electrosurgical handset during cutting and coagulation. When the handset is activated in the gas enhanced mode, an argon gas plasma is created between the electrode and the tissue.	The Indications for Use of the application and predicate devices are the same, both devices are for standard cutting or coagulation; argon enhanced electrosurgery is also available when the handset is activated in the gas enhanced mode. The Argon shrouded mode was included in the device description of the predicate. It allows the use of argon gas to blow smoke out of the surgical field during RF cutting.
Product Code	GEI	GEI	Identical
Technology			
Mechanism of Standard Electrosurgery	The Argon Handset is designed to connect with electrosurgical generator and argon gas delivery system. When standard electrosurgery is activated, the electrosurgical energy will be delivery from electrosurgical generator to the handset electrode, to cut or coagulate in surgical procedures	Same for K964636	Identical

Feature	**Application Device:** Argon Handset	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Mechanism of Argon-Enhanced or Shrouded Operation	The Argon Handset is designed to connect with electrosurgical generator and argon gas delivery system. The argon gas tube serves a gas path for argon gas to flow through to the surgical field. At the distal end of electrode, the argon gas will turn into plasma state and then emit to the target site when the Argon Gas Delivery System is in the "enhanced" mode or the gas will blow out smoke formed during RF cutting when in "shrouded" mode.	Same for K964636	Identical
Energy Used	Radiofrequency Electrical Current	Radiofrequency Electrical Current	Identical
Operation Principle	Monopolar Electrosurgery	Monopolar Electrosurgery	Identical
Operation Gas	Argon Gas	Argon Gas	Identical
Equipment Mated	Electrosurgical Generator: Covidien Force EZ™ or Force FX™ series	Same for K964636	Identical
	Argon Gas Delivery System: Covidien Argon Gas Delivery Unit II or Force™ GSU Argon Gas Delivery System		
Design – Handset Mechanism			
Electrode Configuration	Blade	Blade	Identical
Electrode Length	~17.5mm	~17.5mm	Identical
Electrode Extension/Retraction	Slide Guide	Slide Guide	Identical
Electrode Interchangeable	Yes	Yes	Identical
Control Type	Hand Control	Hand Control	Identical
Activation Mechanism	Rocker Switch	Rocker Switch	Identical
Gas On/Off Control	Slide Switch	Slide Switch	Identical
Cable Set Length	10 ft	10 ft	Identical

Feature	**Application Device:** Argon Handset	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Connection Interface	ESU: banana lead Argon Gas Delivery: gas filter Signal Control: 3-pin connector	Same for K964636	Identical
Argon Gas Flow Rate	up to 12LPM	up to 12LPM	Identical
Design-Handset Electrical Feature			
Handset Insulation	electrosurgical energy line: double layer of polymer handset body: polymer shell	electrosurgical energy line: double layer of polymer handset body: polymer shell	Identical
Electrical Safety	Withstand 5.6kV$_p$ for **High Frequency** breakdown Withstand 5.6kV$_p$ AC at **Main Frequency (60Hz)** breakdown	(unknown, but electrical safety complies with consensus standard)	Identical
Design-Handset Material			
Handset Electrode	Stainless Steel SUS 304	Stainless Steel SUS 302/SUS 304	Functionally Identical
Handset Handle	Nozzle: Aluminum Ceramic Electrode Extension Guide: HDPE Activation Switch: PC Gas Switch: PC Handset Body: HIPS	Nozzle: Aluminum Ceramic Electrode Extension Guide: HDPE Activation Switch: PC Gas Switch: PC Handset Body: HIPS	Identical
Cable Set	Outer Jacket: PVC Argon Gas Tube: PVC Electrosurgical Energy Line: PE+EVA, Copper Signal Control Line: PVC, Copper	Outer Jacket: PVC Argon Gas Tube: PVC Electrosurgical Energy Line: PE+EVA, Copper Signal Control Line: PVC, Copper	Identical
Connectors	ESU: Copper Argon Gas Delivery: Acrylic Signal Control: PVC mold, Copper	ESU: Copper Argon Gas Delivery: Acrylic Signal Control: PVC mold, Copper	Identical
Other Attributes			
Single Use or Reusable	Single use	Single use	Identical
Sterilization	Gamma	Gamma	Identical
Performance/ Safety Testing in accordance with:	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Nearly Identical, Application device in conformance with latest version of the listed Standards

F. Summary of Supporting Data.

New Deantronics has conducted extensive testing to ensure that the subject device met design specifications, functions as intended and conforms to the internationally recognized standards.

Bench Testing

All the test results demonstrate the performance of Argon Handset meets the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Argon Handset is as safe and effective as the predicate device and reference device.

Performance bench testing was conducted in accordance with FDA's guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016. Besides the tests derived from FDA guidance, some internal requirements were conducted to verify the design specification (e.g. electrode slide, activation force, activation overtime, and continuity); and some testing was performed to confirm the integrity and safety of argon gas delivery as well (e.g. gas filter test, impact and back pressures, and HF breakdown with argon gas). Thermal Effects on Tissue testing were conducted to demonstrate adequate performance within a system.

Electrical Safety and Electromagnetic Compatibility Testing

Electrical safety testing was conducted in accordance with:
IEC 60601-1:2005+AM1:2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-2:2017 *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*.

Electromagnetic Compatibility Testing (EMC) was conducted in accordance with IEC 60601-1-2:2014 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.*

The Argon Handset passed all electrical safety and EMC testing.

Shelf-Life Testing

Shelf-life testing was conducted in accordance with FDA's guidance document *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016 and internal requirements. The Argon Handset was subjected to accelerated aging. The aging studies established that the device and packaging remain functional and maintain sterility for 2 years.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009/AC:2010, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA's guidance documents, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued June 16, 2016 and *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016. This testing demonstrates that the materials in the device will not cause a biocompatibility reaction when used as intended.

Package Testing

The argon handset package has been verified and validated in accordance to the associated ASTM package standards. The test result demonstrates the sterile package of argon handset is adequate. After testing, the package integrity remains uncompromised and the sterile barrier is not adversely affected.

Animal Studies

No animal studies were performed as appropriate verification and validation of the device was achieved from the results of the bench performance testing, biocompatibility evaluation, and electrical/safety testing.

Clinical Studies

No clinical studies were performed as appropriate verification and validation of the device was achieved from the results of the bench performance testing, biocompatibility evaluation, and electrical/safety testing.

Conclusion

New Deantronics concludes that the validations demonstrate that the application Argon Handset is in conformance with the latest bench testing and biocompatibility standards and is substantially equivalent to the predicate Valleylab Force Argon II Argon Enhanced Electrosurgical System (K964636).